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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,695

Applicant(s)

REID ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,7-10,12,14-17,19,21-25,27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7,10,12,14,17,19,21,22,25,27 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

This application filed June 11, 2001, is a continuation in part of 09/459,292, filed December 10, 1999, now US Patent 6,479,051.

Applicants' amendment filed September 13, 2004 has been received and entered. Claims 4, 6, 11, 13, 18, 20, 26 and 28 have been canceled. Claims 1, 3, 5, 7, 10, 12, 14, 17, 19, 21, 22, 25, 27 and 29 are pending.

Election/Restriction

Applicant's election with traverse of Group I, claims 3, 5, 7, 10, 12, 14, 17, 19, 21, 25, 27 and 29 in the reply filed on April 5, 2004 was acknowledged. Applicants have canceled claims 4, 6, 11, 13, 18, 20, 26 and 28 drawn to the non-elected invention. No new arguments in traverse of the restriction have been provided. Again it is noted that with respect to group II because it has been claimed in a linking claim, upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Claims 1, 3, 5, 7, 10, 12, 14, 17, 19, 21, 22, 25, 27 and 29, drawn to a method of improving vaginal health comprising delivering a probiotic organism wherein said organism is a *Lactobacillus*, and the product consisting of *L. rhamnosus* GR-1 and *L. fermentum* RC-14 are currently under examination.

Priority

Applicants have not addressed the priority information. As stated previously, Applicant has complied the conditions for receiving the benefit of an earlier filing date under 35 U.S.C.

120. The pending claims are given the priority date of December 10, 1999, the effective filing date of 09/459,292.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 14, 21, 22 and 29 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

The evidence of proper deposit and Applicants' signed statements regarding the availability of the specific strains of *Lactobacillus* strains *L. fermentum* RC-14 and *L. rhamnosus* GR-1 has satisfied the deposit requirements and addressed the basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Linking claim 1 is rejected under 35 USC 102(b) as being anticipated by Ford *et al.* (5,635,202) or Velraeds *et al.* (App Env Microbiol 62(6):1958-1963, June 1996).

Applicants summarize the teachings of Ford *et al.* and Velraeds *et al.* And argue that neither Ford *et al.* nor Velraeds *et al.* teach the oral administration of a probiotic. See Applicants' amendment, page 7. Applicants' arguments have been fully considered, but not found persuasive.

Examiner agrees with Applicants summary of the specific experiments detailed in Ford *et al.* and Velraeds *et al.* However, beyond the specific experiments each disclose that each has and can be administered orally. For example Velraeds *et al.* teach in the introduction that specific strains in dairy products produce the surfactants under investigation. Further, in the summary Velraeds *et al.* teaches specifically that they have been administered in a variety of means, including orally (page 1963, top of first column). Further, beyond determining the specific mechanism of activity, both Ford *et al.* (5,635,202) and Velraeds *et al.* Teach the importance of the micro flora in the urogenital tract of the female, and how the unbalance results in increased infection. Thus, because each teach the use of lactobacillus for the colonization of the urogenital

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tract to prevent and treat colonization of uropathogenic flora, and that administration can be done orally, both Ford *et al.* (5,635,202) or Velraeds *et al.* anticipate the linking claims.

In addition, it should be noted that the linking claims broadly encompass administration by any route including orally because of the open language encompassed by “comprising” recited in the claims. Moreover, a reasonable interpretation of the claims indicates that the claims encompass a woman eating yogurt (a food grade source) with live acidophilus and bifidus cultures (see species in claim 5 for example).

Claims 1, 3, 5, 7, 10, 12, 14, 17, 19, 21, 22, 25, 27 and 29 stand rejected under 35 USC 102(b) as being anticipated by Reid *et al.* (5,645,830).

Applicants summarize the teachings of Reid *et al.* and argue that Reid *et al.* do not teach the oral administration of a probiotic. See Applicants’ amendment, pages 7-8. Applicants’ arguments have been fully considered, but not found persuasive.

A review of the teachings of Reid *et al.* teaches that the “actual composition can be instilled in the form of a freeze dried preparation, cream, paste, gel, liquid or suppository for intestinal, oral, vaginal, urethral or periurethral instillation.” (paragraph 13). Contrary to Applicants arguments, Reids *et al.* teaches compositions for the oral administration. As staed previously, Reid *et al.* teach to use *L. rhamnosus* GR-1 (see for example claim 8) for the treatment and prevention of a variety of urogenital microbial infections. It appears that *L. fermentum* RC-14 is also termed or is a variation of *L. acidophilus* RC-14 (as evidenced by Velraedes *et al.* in light of Heinemann *et al.* FEMS Micro. Let. 190:177-180, 2000 page 177, ref. [7])

Therefore, Reid *et al.* teach species recited in the claims and thus, anticipate the claims.

Claims 1, 3, 5, 7, 10, 12, 14, 17, 19, 21, 22, 25, 27 and 29 stand rejected under 35 U.S.C. 102(b) as being anticipated by Reid *et al.* (Clin. Micro. Rev. 335-344, 1990).

Applicants summarize the teachings of Reid *et al.* and argue that Reid *et al.* do not teach the oral administration of a probiotic. See Applicants' amendment, pages 8-9. Applicants' arguments have been fully considered, but not found persuasive.

As argued above, Examiner agrees with Applicants summary of the specific experiments detailed in Reid *et al.* However, beyond the specific experiments the reference discloses that *Lactobacillus* was and can be administered orally. Reid *et al.* teach to use *Lactobacillus* for the treatment and prevention of a variety of urogenital microbial infections including vaginitis (page 340). More specifically, Reid *et al.* teach to use *L. casei* GR-1 (page 339) which also appears to be termed *L. rhamnosus* GR-1 for the treatment and prevention of a variety of urogenital microbial infections.

Therefore, Reid *et al.* teach a species recited in the claims and thus, anticipate the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 5, 7, 10, 12, 14, 17, 19, 21, 22, 25, 27 and 29 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,479,051.

Applicants argue that the amendments to the claims has obviated the basis of the rejection. See Applicants' amendment, pages 9-10. Applicants' arguments have been fully considered, but not found persuasive.

As noted by Applicants, the same methodology is used in each case, and Examiner acknowledges that the method have different intended uses, however the method steps are not distinguishable from one another. Moreover, as taught in the disclosure a flora that is unbalanced can lead to infection and conversely an improved urogenital flora will be effective in restoring its proper status. It is maintained that although the conflicting claims are not identical, they are not patentably distinct from each other because the methods that establish a healthy urogenital flora is the same conditions that improve vaginal health as instantly claimed. The guidance for administration and types of probiotics taught in each specification are the same, and each recite the administration of "at least one" (claim 1) allowing for the administration of more than one anticipating the instant invention that recites the administration of a second probiotic organism and is obvious in light of the teachings of the specification.

Conclusion

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No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


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